**REMARKS**

Claims 1, 5-7, 10-12 and 14-17 currently appear in this application. The Office Action of October 16, 2003, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicants respectfully request favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

**Specification**

The specification is objected to because there are two identical descriptions for Figure 26.

The specification has been amended to delete the redundant paragraph.

**Double Patenting**

Claims 1-17 are rejected under the judicially created doctrine of double patenting as being unpatentable over claims 1-8 and 15-17 of Ishida et al., U.S. Patent No. 6,406,566.

This rejection is respectfully traversed. Claim 1 has been amended by incorporating the limitations of claims 2, 3 and 4; claim 7 has been amended to incorporate the limitations of claims 8 and 9; claim 12 has been amended to incorporate the limitations of claims 13 and 14.

In claim 1 as amended, the recitation both "and an intermediate portion between said body portion and said tip end portion at a temperature continuously or stepwise changing from the heating temperature of said body portion to the heating temperature of said tip end portion" and "said intermediate body portion having rigidity continuously or stepwise changing from said high-rigidity body portion to said low-rigidity tip end potion" is supported by the specification as filed at page 6, liens 3-6 (paragraph [0016]) and page 18, lines 2-6.

In claim 7 as amended, the recitation "wherein said metal pipe is formed by hot working and cold working, maintained at a temperature of at least 500°C and rapidly quenched, and then subjected to an aging treatment at a temperature distribution that decreases continuously or stepwise in a direction from a base end to a tip end of the catheter, wherein the highest temperature is 250-350°C and the lowest temperature is lower than 250°C in said temperature distribution, and wherein said catheter is relatively rigid in a body portion and has low rigidity in a tip end portion, and said metal pipe has a bending modulus which decreases continuously or stepwise in a direction from a base end to a tip end of the catheter" find support in the specification as filed in paragraphs [0098], [00101], [00102] and [00103].

It is respectfully submitted that claims 1, 5-7, 10-12 and 14-17 as amended are patentably distinct from claims 1-8 and 15-17 of Ishida et al. claim 1 as amended calls for "A core wire for a guide wire comprising a body portion having high rigidity and a top end portion having a lower rigidity than that of said body portion, at least part of said core wire being made of a copper-based alloy comprising 3-10 weight% of Al and 5-20 weight % of Mn, the balance being substantially Cu and inevitable impurities,

Wherein said copper-based alloy wire is formed by hot working and cold working, maintained at a temperature of at least 500˚C and then rapidly quenched, and further subjected to an aging treatment comprising heating the high-rigidity body portion at a temperature of 250-350°C, heating the tip end portion at a temperature of less than 250°C, and an intermediate portion between said body portion and said tip end portion at a temperature continuously or stepwise changing from eth heating temperature of said body portion to the heating temperature of said tip end potion, and

Wherein said copper-based alloy wire comprises a high-rigidity body portion, a low-rigidity tip end portion, and an intermediate portion between said high-rigidity body portion and said low-rigidity tip end portion, said

intermediate portion having rigidity continuously or stepwise changing from said high-rigidity body portion to said low-rigidity tip end portion."

That is, as described in the specification of the present invention at paragraphs [0014], [0015], [0016], etc., the present invention aim to provide a functionally graded Cu-Al-Mn alloy core wire for a guide wire comprising a body portion having high rigidity and a tip end portion having a lower rigidity than that of the body portion so as to continuously or stepwise change the physical properties from the high=-rigidity body portion to the low-rigidity tip end potion while exhibiting remarkably gradient properties obtained by applying an aging treatment in a gradient temperature heater to a shape memory Cu-Mn-Al alloy having a beta-phase structure disclosed in Ishida et al., which corresponds to JP 7-62472.

Specifically, Ishida et al. disclose a copper-based alloy having shape memory properties and super elasticity, wherein the copper-based alloy has a recrystallization structure substantially composed of beta-single phase having crystal orientation aligned in a cold-working direction (see claims 1 and 2). Also, the copper-based alloy of Ishida et al. has a composition comprising 3-10

weight% of Al, 5-20 weight% of Mn, the balance being inevitable impurities, and further comprises at least one element selected from the group consisting of Ni, Co, Fe, Ti, V, Cr, Si, Nb, Mo, W, Sn, Sb, Mg, P, Be, Zr, B, C, Ag and misch metals in a total amount of 0.001-10 weight % based n the copper-based alloy of 100 weight % (see claims 3 and 4).

Further, Ishida et al. disclose a wire made of the copper-based alloy disclosed herewith, wherein eth copper alloy has an average grain diameter equal to or more than the radius of the wire, or wherein a region of the wire, in which the copper-based alloy has a grain diameter of equal to or more than the radius, has a length of 30% or more based on the entire length of the wire (see claims 5 and 6). Still further, Ishida et al. disclose not only a guide wire for a catheter composed of the wire claimed herein, but also a twisted wire composed of the wire claimed therein (see claims 7 and 8).

In the method for producing the copper-based alloy of Ishida et al., the microstructure of the alloy is preferably transformed into alpha + beta dual phase comprising alpha-phase of 20 volume % or more prior to cold working, and followed by cold working in a maximum cold-working ratio of 30% or more, and subjecting the cold-worked alloy to a solution treatment at least once, a quenching and an aging

treatment to obtain the copper-based alloy having a recrystallization structure substantially composed of beta-single phase having crystal orientation aligned in a cold-working directions (column 2, lines 43-50). Further, Ishida et la. Teach than the ageing treatment is preferably carried out at a temperature of 250°C or lower for 1-300 minus in order to stabilize the martensitic transformation temperature (see column 8, lines 46-61).

However, Ishida et al. merely teach a copper-based alloy composed of beta-single phase having shape memory properties and super elasticity, or a wire made of the copper-based alloy thereof, etc., and there is no disclosure or suggestion of a core wire having different hardness and rigidity at the tip end portion and the body portion thereof. Moreover, Ishida et al. fail to teach or suggest that the intermediate portion between the tip end and the body portions has gradient mechanical properties continuously or stepwise changing from the tip end portion to the body portion thereof obtained by increasing the hardness and rigidity of eth core wire either by using age hardening at 250-350°C of by applying an aging treatment in an electric furnace having a temperature gradient to the shape memory Cu-Al-Mn alloy thereof.

In contrast to the alloy of Ishida et al., the functionally graded Cu-Al-Mn alloy of the present invention as recited in claim 1 provides a core wire for a guide wire comprising a high-rigidity body, portion, a low-rigidity tip portion, and an intermediate portion having rigidity continuously or stepwise changing from the high-rigidity body portion to the low-rigidity tip end portion. This is achieved by applying an aging treatment in a gradient temperature heater as described in the specification at paragraphs [0073] *et. seq.* of the present invention.

Thus, the herein claimed invention is a copper-based alloy wire which is formed by hot working and cold working, maintained at a temperature of at least 500°C and then rapidly quenched, and further subjected to an aging treatment comprising heating the high-rigidity body portion at a temperature of 250-350°C, heating the tip end portion at a temperature of less than 250°C, and an intermediate portion between the body portion and the tip end portion at a temperature continuously or stepwise changing from the heating temperature of the body portion to the heating temperature of the tip end portion, thereby making it possible not only to obtain a high hardness and a high rigidity from the alloy composed essentially of an alpha-phase and a Heusler phase, but also to provide a functionally graded Cu-Al-Mn alloy core

wire for a guide wire comprising a body portion having high rigidity and a tip end portion having a lower rigidity than that of the body portion so as to continuously or stepwise change the mechanical properties from the high-rigidity body portion to the low-rigidity tip end portion with remarkably gradient properties.

As is clear from the foregoing, the core wire for a guide wire comprising a body portion having high rigidity and a tip end portion having a lower rigidity than that of the body portion, and an intermediate portion there between having the gradient properties of eth claimed invention is completely different from the wire claimed in Ishida et al.

One skilled in the art, reading Ishida et al, Would not be motivated to achieve the present invention, as there is nothing in Ishida et la. That even suggests a Cu-Al-Mn alloy wire which has different properties along the length of the wire.

Claim 7 as amended calls for "A catheter at least partially comprising a metal pipe, said metal pipe being made in at least a tip end portion thereof of a copper-based alloy comprising 3-10 weight% of Al and 5-20 weight % of Mn, the balance being substantially Cu and inevitable impurities,

Wherein said metal pipe is formed by hot working and cold working, maintained at a temperature of at least 500°C and rapidly quenched, and then subjected to an aging treatment at a temperature distribution that decreases continuously or stepwise in a direction from a base end to a tip end of the catheter, wherein the highest temperature is 250-350°C and the lowest temperature is lower than 250°C in said temperature distribution, and

Wherein said catheter is relatively rigid in a body portion and has low rigidity in a tip end portion, and said metal pipe has a bending modulus which decreases continuously or stepwise in a direction from a base end to a tip end of the catheter."

That is, as described in the specification of the present application beginning at paragraph [0013], the claimed invention is designed to provide a functionally graded Cu-Al-Mn alloy catheter comprising a soft tip end portion and a properly elastic and rigid body portion so as to decrease the bending modulus continuously or stepwise in a direction from a base end to a tip end of the catheter obtained by applying an aging treatment a gradient temperature heater to the metal pipe of the shape memory Cu-Al-Mn alloy having a beta-phase structure disclosed in Ishida et al.

It is true that Ishida et al. disclose and claim a pipe made of the copper-based alloy described therein (see claims 15-17), but Ishida et al. merely use a copper-based alloy composed of beta-single phase having shape memory properties and super elasticity, or a pipe or a catheter made therefrom. However, the copper-based alloy of Ishida et al. does not have differing hardness and rigidity at the tip end portion and the body end portion thereof, nor the gradient properties there between.

In contrast to Ishida et al., the functionally graded Cu-Al-Mn alloy of the present invention as recited in claim 7 provides a catheter which at least partially comprises a metal pipe made of this alloy, the metal pipe having a bending modulus which decreases continuously or stepwise in a direction from a base end to a tip end of the catheter, which is obtained by aging treatment in a gradient temperature heater as described in the specification beginning at paragraph [0073].

The properties of the herein claimed metal pipe can be attained by hot working and cold working, maintaining the alloy at a temperature of at least 500°C and rapidly quenching the alloy, and then subjecting the alloy to an aging treatment at a temperature distribution that decreases

continuously or stepwise in a direction from a base end to a tip end of the catheter, wherein the highest temperature is 250-350°C and the lowest temperature is lower than 250°C, thereby making it possible to achieve a high hardness and a high rigidity from the alloy composed essentially of an alpha-phase and a Heusler phase as well as to provide a metal pipe for a catheter having a gradient of hardness and rigidity from the base end portion to the tip end portion. This aging treatment in a gradient temperature heater makes it possible to achieve this hardness gradient.

As is clear from the foregoing, the catheter having the gradient properties as claimed herein is different from the catheter composed of the pipe made from the copper-based alloy disclosed in Ishida et al. There is neither teaching nor suggestion in Ishida et al. of this type of catheter. Therefore, one skilled in the art reading Ishida et al. would not be motivated to make the invention recited in claim 7 as amended, and therefore it is respectfully submitted that claim 7 is not obvious over Ishida et al.

Claim 12 of the present invention calls for "A catheter containing a reinforcing metal member in at least part of a catheter tube, said reinforcing metal member being made of a copper-based alloy comprising 3-10 weight % of Al

and 5-20 weight % of Mn, the balance being substantially Cu and inevitable impurities,

Wherein said reinforcing metal member is formed by hot working and cold working, maintained at a temperature of at least 500°C and rapidly quenched, and then subjected to an aging treatment at such a temperature distribution that decreases continuously or stepwise in a direction from a base end to a tip end of said catheter, wherein the highest temperature is 250-350°C and the lowest temperature in said temperature distribution is less than 250°C, and

Wherein said reinforcing metal member has a bending modulus which decreases continuously or stepwise in a direction from the base end to a tip end of said catheter."

That is, as described in the specification of the present application at paragraphs [0020] and [0149] *et seq.*, the claimed invention provides a catheter containing a reinforcing metal member of a functionally graded alloy comprising a soft tip end portion and a properly elastic and rigid body portion so as to continuously of stepwise change the physical properties from the rigid body portion to the tip end portion embedded as a Cu-Al-Mn alloy braid layer in a tube made of a material such as nylon.

In contrast thereto, Ishida et al. is silent wither respect to a catheter containing a reinforcing metal member, or any reinforced catheter tube of the type claimed herein. Accordingly, one skilled in the art reading Ishida et al. would not be motivated to reach the catheter recited in amended claim 12.

Claims 1-17 are rejected as being obvious over Palermo in view of Tabei.

This rejection is respectfully traversed. Palermo teaches that the conventional catheter guide wire is tapered along its length to allow great flexibility in that remote region of the guide wire (see column 1, lines 60-67; column 5, lines 20-27; and Figure 1). Further Palermo discloses a guide wire having a body portion relatively high in rigidity and a distal portion (tapered portion) which is relative flexible (column 2, lines 16-30).

However, Palermo fails to disclose that the guide wire continuously or stepwise increases in rigidity from the tip end to the body portion. Palermo also fails to disclose a functionally graded Cu-Al-Mn alloy core for a guide wire comprising a tip end potion having super elasticity and soft and scarcely plastic deformable property by applying a tapered processing if necessary, and a body portion having

high rigidity acquired by applying a temperature gradient in a gradient temperature heater and an intermediate portion there between having the gradient properties continuously changing from the high-rigidity body end portion to the low-rigidity tip end portion.

Palermo discloses Ni-Ti alloys used for core wires of the guide wire used in the Palermo catheter. However, the tip end portion of the core wire in Palermo is either soft or flexible since the distal end section of the wire is formed of super-elastic metallic materials or tapered along the length of the wire. In Palermo, the body portion is not significantly more rigid than the tip portion. The differences in rigidity in the Ni-Ti alloy of Palermo are far less than required for the present invention. The deflection of the Palermo alloy is illustrated in Figure 1c, submitted herewith. Furthermore, in the stainless steel core wire disclosed in Palermo, the tip end portion thereof has a high rigidity, as shown in accompanying Figure 1d, but it does not exhibit a super elastic behavior, so there is a large possibility of causing plastic deformation of the low-rigidity tapered portion.

In contrast to these convention core wires, in the functionally graded Cu-Al-Mn alloy of the present

invention, the tip end portion exhibits a super elasticity and is significantly made soft by tapering and thus it is not easily susceptible to plastic deformation. Moreover, the harness, tensile strength, rigidity, etc. which are inherently possessed properties in the alloy *per se* can be greatly increased in the tip end portion from the low-aging temperature portion to the high-aging temperature portion by applying an aging treatment in a gradient temperature heater (see Tables 2 and 3 at page 30 of the instant specification).

As is clear from the above, the functionally graded Cu-Al-Mn alloy core wire of the present invention is quite different from the core wire for the guide wire made of a stainless steel alloy or a high elasticity metal such as Ni-Ti alloy of Palermo. One skilled in the art reading Palermo would not be motivated to reach the herein claimed invention, as Palermo does not disclose a wire having a rigidity gradient.

Tabei adds nothing to Palermo to render the herein claimed invention obvious. Tabei teaches that the shape memory characteristics of a Cu-based shape memory alloy can be improved. The alloy in Tabei consists essentially of 15-35 weight % Zn, 3.2-10 weight % Al, 0.01-1 weight % Si, and at least one element selected from the group consisting of

0.5-2 weight % Ti, 0.01-1 weight % Cr, 0.01-8 weight % Mn, 0.01-2 weight % Co, 2.1-4 weight % Ni, the balance being Cu and inevitable impurities, particularly, significantly improved resistance to intercrystalline cracking in the grain boundary by the deposition of the fine grains of the Si-intermetallic compound and the improvement in the heat cycle characteristics thereof while maintaining the inherent good shape-memory properties (see column 1, line 55 to column 2, line 9). That is, Tabei merely discloses a method for improving the metal characteristics by the deposition of the intermetallic compound, which is completely different from the present invention in generating gradient properties in the shape memory, functionally graded Cu-Al-Mn alloy.

Tabei describes that, after casting the alloy to an ingot, the ingot is subjected to routine hot and cold working, followed by a solution treatment at a temperature of 580-850`C (see column 2, line 65 to column 3, line 58). However, Tabei fails to teach or suggest not only the improvement of the rigidity and hardness of the shape memory alloy by using an aging treatment, but also the formation of the functionally graded alloy using a gradient temperature heater for allowing the shape memory copper alloy to have gradient properties. Further, Tabei is silent regarding a catheter comprising a metal pipe made of the alloy and a

catheter tube reinforced with the copper alloy braid. Moreover, it should be noted that the composition of the copper alloy in Tabei is significantly different from that of the present invention, because of the presence of an excess of 15-35 weight % zinc.

Palermo teaches a composite guide wire jacketed with a thin coil or a braid of a super-elastic ribbon at the distal portion of the conventional catheter guide wire (column 4, lines 26-39). However, Palermo is silent regarding the hardness and the rigidity at the body portion of the wire.

In contrast thereto, claims 5 and 6 of the present application relate to a guide wire completely made of the functionally graded Cu-Al-Mn alloy core wire recited in claim 1 as amended comprising a tip end portion which is soft, a body portion having a high rigidity, and an intermediate portion between the tip end portion and the body portion having gradient properties continuously changing there between. In the guide wire of the present invention, the softer the tip end portion thereof or the more difficult to cause a plastic deformation, and the greater the tensile strength and the rigidity of the body portion, the better the operability of the guide wire and/or the controllability of the torque conveyance at the physician's hand. Accordingly,

the guide wire made of the functionally graded Cu-Al-Mn alloy of the present invention is significantly improved in the operability of the guide wire and the controllability of the torque conveyance, as shown in Figure 2 submitted herewith.

Figure 2(a) is a schematic diagram for evaluating the operability of a guide wire and the controllability of the torque conveyance by examining the relation between a driving angle at the body portion and a follow-up angle at the tip end portion of the guide wire inserted into a Teflon tube with two turns; and

Figure 2(b) shows an evaluation of the results of eth operability and the controllability of the torque conveyance.

In the Ni-Ti guide wire, because of the low rigidity at the body portion, the follow-up at the tip end portion thereof is so poor that the follow-up angle suddenly changes in a great range when a driving angle varies largely to show a Whipping phenomenon, indicating the inferiority in the operability of the guide wire and the controllability of the torque conveyance. However, in the Cu-Al-Mn guide wire made of the functionally graded alloy of the present invention which is higher in rigidity at the body portion, the follow-up at the tip end portion is good, indicating the superiority in

the operability of the guide wire and the controllability of the torque conveyance.

In contrast thereto, the guide wire disclosed in Palermo has high flexibility in the distal section due to the tapering and high column strength due to the presence of the super-elastic braid. However, the tensile strength and the rigidity at the body portion are poor, thereby making it impossible to achieve the sufficient operability and controllability of the torque conveyance. Practically, the guide wire made of the fractionally graded alloy of the present invention is superior in both operability and controllability of the torque conveyance than those made of the Ni-Ti alloy core wire of Palermo, as illustrated in figure 2. Also, in he case of the guide sire made of a stainless steel core wire, as mentioned previously, there is a great possibility to case a plastic deformation at the tapered low-rigidity tip end portion, so that the targeted site in a lumen system such as blood vessels can be injured by the plastic-deformed distal end section thereof, when eth plastic-deformed guide wire is rotated or pushed out, even though the tip end portion of the guide wire is jacketed with the super-elastic alloy ribbon.

The functionally graded Cu-Al-Mn alloy of the present invention makes it possible to obtain flexibility at the tip end portion end high rigidity at the body portion, neither of which can be accomplished with the guide wires of Palermo. Tabei adds nothing to Palermo, as Tabei discloses a significantly different alloy and fails to teach or suggest the concept of a rigidity gradient.

Palermo teaches that in the guide wire made or Ni-Ti alloy or a stainless steel core wire, the tapered tip end portion thereof is partially coated with suitable radiopaque metals (column 4, lines 6-25 and column 6, lines 1-15). However, since the core wire for the guide wire in the present invention is made from the functionally graded alloy claimed in claim 1, the disclosure in Palermo is irrelevant.

As is clear from the foregoing, the guide wire comprising a core wire made of the functionally graded Cu-Al-Mn alloy of the present invention is completely different from the guide wire made of Ni-Ti alloy or a stainless steel core wire disclosed in Palermo. Tabei adds nothing to Palermo, because the alloy of Tabei is different from that of the present invention, and the alloy of Tabei is not functionally graded.

Amended claim 7 of the present application recites a catheter having gradient properties made of a functionally graded Cu-Al-Mn alloy pipe. Palermo merely disclose a guide wire made of Ni-Ti alloy or a stainless steel core wire. There is nothing in Palermo regarding any catheter made of a Cu-Al-Mn pipe. Tabei adds nothing to Palermo, as Tabei has nothing to do with catheters.

Amended claim 12 of the instant application recites a catheter containing a reinforcing metal member of the shaped memory, functionally graded Cu-Al-Mn alloy comprising a soft tip end portion, a properly elastic and rigid body portion and an intermediate portion there between having the physical properties continuously or stepwise changing from the rigid body portion to the tip end portion embedded as a Cu-A-Mn alloy braid layer in a tube body such as nylon or the like. Palermo fails to teach or suggest any catheter reinforced in this manner. As noted above, Tabei adds nothing to Palermo, as Tabei has nothing to do with catheters.

It is clear from the above that the combination of Palermo and Tabei neither teaches nor suggests a core wire for a guide wire comprising a memory shape, functionally graded Cu-Al-Mn alloy having a high rigidity portion at the

body portion, a low rigidity tip end portion, and an intermediate portion between them having the gradient properties which change from the high-rigidity body to the low-rigidity tip which is obtained by applying an age treatment in a gradient temperature heater to the corresponding memory shape Cu-Al-Mn alloy, a catheter comprising a metal pipe of the memory shape, functionally graded Cu-Al-Mn alloy as such and a catheter tube reinforced therewith, with are important features of the present invention.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

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